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The Impact of Biologics and Biosimilars on Chronic Disease Management

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Abstract:

In the last 30 years, medicines containing live biological ingredients have changed the treatment of many diseases. Other than a few cancers, these medicines have cured rheumatoid arthritis, psoriasis, Crohn's disease, multiple sclerosis, etc. Unlike traditional small-molecule medicines, which have general and varied effects, biologics have a much more specific action. They act more like a missile locking on to a target. Many biologics have been launched as off-patent medicines which has ushered a greater number of such drugs Biosimilars are substances that act like a reference biologic. They are as good as the reference biologics in other words. The FDA says biosimilars must have similar genetic characteristics, this is important to guarantee that they are effective and safe. There have been a few biosimilars in the market and their availability is only increasing. An informative guide on biosimilars and biologics for providers and patients. Though these may curb healthcare costs, and enhance availability, the healthcare provider and patient awareness of biosimilars and biologics are vital as it safeguard modern medicine. This study looks into the impact on therapy, money, and ethics caused by biosimilars and looks at chronic disease specifically.

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INTRODUCTION

Biologics are big, complex drugs that are derived or manufactured from living organisms (Makurvet, 2021). They are difficult to create, replicate, and characterize in the same way typical chemical drugs can, but can also be more beneficial. Biosimilars are very similar, but not exact duplicates of biologics (Patel *et al.*, 2023). Insurmountable natural variability of biologics causes them to never be compared as the same, hence the word “biosimilar” is used to signify something as being highly similar (Hanly and Lethbridge, 2021). Tried and tested regulatory processes exist to govern the development and use of biologics, and very similar processes exist for biosimilars as well. Biopharmaceuticals and recent developments in biotechnology are two terms that have been utilized often to describe biologics and biosimilars (Park *et al.*, 2022). Biologics have been in widespread use in medicine since 1982 and now represent one-third of all new FDA drugs, despite making up just 2% of the market. Biologics can be monoclonal antibodies, interferons, interleukins, or other large proteins, peptides, or sugars, as long as they are not the product of viruses or a single chemical formula (Zaynab *et al.*, 2018; Zhao *et al.*, 2022). These monoclonal antibodies (mAbs) are the most common form of biologic drugs and biosimilars (Iqbal *et al.*, 2018; Yamamoto *et al.*, 2022). Since 2013, thirteen such biosimilar mAbs have been okayed by the World Health Organization (Uhlig and Goll, 2017). Biologics often greatly improve the quality of life or increase survival in many conditions (Yamamoto *et al.*, 2022). Just one of many examples is Humira, a biologic drug for Rheumatoid Arthritis (RA) introduced in 2003. Its increased use for the treatment of RA has coincided with a downtrend in the RA mortality rate per 100,000 people since 1999 (van Linschoten *et al.*, 2021). Despite their often necessary applications, due to their complexity and the nature of chronic diseases, biologics are more expensive and involved to produce, store, transport, analyze, and prescribe than typical chemical drugs. They are generally used as a later option to treat a disease when other more general/less high-cost medications are exhausted (Lowe *et al.*, 2021). Owing to these and other factors, despite many advances stemming from the introduction of biologic drugs to medicine, not everyone with a chronic disease is being provided access to necessary care and quality of life-enhancing medications (van Linschoten *et al.*, 2021). Thus, patient accessibility is a point of concern and an area of focus in the future push for improvement and standardization of quality biologics and biosimilars. Given biologics’ increasing prevalence and importance have been well recognized, and the topic and parameters of biosimilars and related fields of discussion have been well defined, there is still much to understand and elucidate among nonspecialists, health policymakers, drug developers, and many more. Hopefully the following will provide an adequate introduction and understanding of 1) the development, use, utility, and concerns in biologics, and 2) the recent advent and concerns in biosimilars (Yamamoto *et al.*, 2022). With this foundation, awareness can be better informed and decisions made to properly appreciate, regulate, and utilize these extremely influential technologies shaping future healthcare (Lowe *et al.*, 2021).

Applications of Biologics and Biosimilars in Chronic Disease Management

Biologic therapies are widely recognized for their efficacy in managing chronic diseases, and their potential, considerable benefits have made them a growing part of many therapeutic landscapes. Biologics can be used for a variety of conditions, from rheumatoid arthritis, diabetes, multiple sclerosis, and more (Singh *et al.*, 2021). Clinical evidence and case studies have demonstrated the efficacy and safety of biologic therapy, often significantly increasing the effectiveness of other treatments (Burr *et al.*, 2022; Iqbal *et al.*, 2021). The mechanism of action by biologic therapy is

well understood as they directly target pathogenic pathways to block inflammatory signals (Chopade *et al.*, 2023; Cohen *et al.*, 2021). However, other biologic therapies target different inflammatory pathways, but the therapeutic benefits are similar (Brusselle and Koppelman, 2022; Iqbal, 2021). This is where biosimilar therapy may come in, as it offers treatments to patients that are similar at a lower cost compared to biologic medicines (De Corso *et al.*, 2021; Uhlig and Goll, 2017). Biosimilar therapy has the potential to expand the range of available treatments, improve patient adherence, and potentially lower costs (Barberio *et al.*, 2023). At the same time, research has shown that the therapeutic benefits of biologic therapy often come in the first months of starting treatment (Dörner *et al.*, 2016). Moreover, biologic therapies could be seen as part of the larger trend in medicine toward increasingly personalized treatments (Fokkens *et al.*, 2023; Jones and Hunter, 2021).

Twelve years ago, following the late-stage failure of leading biopharmaceutical compounds, it seemed as if the EU's hope of developing new European blockbuster drugs was gone (Karimov, 2024). This trend seemed somewhat ironic given that the shift to "tailor-made" bioengineered drugs, or biologics, – ranging from antibodies and fusion proteins to vaccines and gene-and-cell therapeutics – seemed to suggest the very opposite direction: toward more and less stringent individual, quite often the multinational regulatory oversight and prohibitively high R&D costs (Van der Meer *et al.*, 2023).

Challenges and Opportunities in the Use of Biologics and Biosimilars

Biologic medications (biologics) are complex macromolecular drugs that are manufactured via living systems and have uniquely complex chemical structures (Vargason *et al.*, 2021). They are composed of sugars, proteins, nucleic acids, or combinations of these substances derived from humans, animals, or microorganisms (Khalilov, 2023). Typically produced by biotechnology, biologics inhibit or enhance vital cellular growth mechanisms and have emerged as promising targeted therapeutic options to treat a wide range of severe and chronic diseases (Kabir *et al.*, 2019). The development of targeted biologics has thus heralded a new era that revolutionizes several treatment modalities (Yusuf *et al.*, 2023). However, the same uniqueness and complexity of the biologics give rise to a host of intentional and unintentional product-related variants that may impact the safety and efficacy of the therapy (Sargazi *et al.*, 2022). The variability of the biological drugs themselves, as well as the variable response of the patients, are the main apprehension in the utilization of such sophisticated therapeutic molecules (Cun *et al.*, 2021). Furthermore, as brand-name biologics are significantly expensive, there is a compelling need to explore cheaper alternatives to broaden patient access and reduce treatment costs (Zain *et al.*, 2022). Bioengineered cost and high value the large and diverse biologics are some medical challenges to the healthcare industry, which has a difficult time affording the therapy and lesser efficacy experimental results (Lee and Lo, 2024). The rise of economic resources from the increasing side of demand is unable to burden the government healthcare system for the many healthcare industries (Mukherjee *et al.*, 2022). It is possible to hinder the massive exploitation of beneficial biological drugs. Thus an alternative solution is the impaired development of bioengineered pegylated therapies for increasing traditional or patent medications with a defect temporary as a result of the effectiveness and the affordability prices (Kheraldine *et al.*, 2021). After the patent expiration of biological products, biosimilar companies can jump into the market with cheaper alternatives which is economically beneficial for states such as the United States and some others in the European Union. The acceptance of generic drug products commercially based on the evidence of the price reduction as transfers, but all antibiotics are not medical bioequivalence safety and efficacy products similar to the innovator reference drugs (Aguirre-Ramírez *et al.*, 2021). Demands for stringent regulatory requirements in this region were striking the healthcare, pharmaceutical industry, and the government regulatory jurisdiction with intense burden (Kheraldine *et al.*, 2021). To ensure the best pharmaceutical

products and the variability or advertising drug in the market, it is also essential to the harmonies of the goods they manufacture to manage regulatory requirements among national and international agencies (Mukherjee *et al.*, 2022). In order to reduce the risks associated with biosimilars and guarantee that complex pharmaceutical therapy is followed, studies have suggested that both the patients and the healthcare professionals involved in the therapeutic process should receive thorough targeting and develop the necessary awareness. The results design an intensive report on the acceptations of the Indonesian pharmaceutical companies containing similar complex ideas market disputes (Aguirre-Ramírez *et al.*, 2021).

Future Directions and Concluding Remarks

Chronic disease management presents complex challenges for both patients and healthcare providers alike (Makurvet, 2021). Aside from the debilitating physical symptoms that accompany conditions like Rheumatoid Arthritis (RA) and Psoriasis, the psychological distress associated with symptom exacerbations can be equally severe (Herrlinger and Stange, 2021). The introduction of biologics in the late 20th century offered meaningful relief to many patients (Durán-Lobato *et al.*, 2021). As with any technological advance, however, a host of new difficulties have subsequently emerged (Uhlig and Goll, 2017). The rise of costly pharmaceuticals has necessitated the creation of more cost-effective iterations. The biosimilar market has exploded in response, and the implications of this shift warrant further consideration as these medications grow ever more prevalent (Kabir *et al.*, 2019).

As the world population continues to age, the incidence of chronic health conditions is expected to rise concomitantly (Kabir *et al.*, 2019). In this context, the demand for long-term medication options is set to increase dramatically (Higgins *et al.*, 2021). The more traditional small-molecule medications that have dominated the pharmaceutical market are slowly being eclipsed by delicate, high-quality macromolecules. To this end, biologics have come to occupy a unique niche within the pharmaceutical research community (Huang *et al.*, 2021). These medications are derived from living or newly modified biologic sources and can fill previously unmet treatment roles (Ashraf and Iqbal, 2022; Celebi Sozener *et al.*, 2022; Iqbal and Irfan, 2021).

For many chronic diseases, biologics now represent the state of the art in long-term care. However, biosimilars have the potential to fundamentally shift power relations currently favoring a handful of corporate entities (Diotallevi *et al.*, 2022). Following the expiration of proprietary rights for biologics, an ever-growing number of companies are free to manufacture biosimilars (Chwalisz and Levy, 2022). Given that these medications share identical active properties, a price decrease can be expected through increased competition (Wechsler *et al.*, 2021). Industrial competition and capitalist markets are complex systems, however, and a clearer testimony of how these changes stand to influence both patients and healthcare workers in future years is warranted (Freitas-Ribeiro *et al.*, 2022).

CONFLICT OF INTEREST

Authors hereby declare that they have no conflict of interest.

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